Central haemodynamics for the therapeutic management of hypertension



<u>March 2015</u>

AMA accepts recommendation for Category 1 CPT Code for arterial pressure waveform assessment

application by the Renal Physicians Association

This code is reserved for procedures with demonstrated clinical efficacy, are performed by many clinicians across the US and, have US FDA approval



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REVIEW

Central pressure should not be used in clinical practice



Gary F. Mitchell*

Thus, currently available evidence does not provide sufficient justification for widespread adoption and routine use of central pressure measurements in clinical practice.

Tonometry central BP



Brachial cuff central BP



Cuff-derived central BP

Devices available	Pro's	Con's
 SphygmoCor XCEL (AtCor, AU) Mobil-o-graph (IEM, DE) Watch BP Office Central (Microlife, CH) Centron cBP301 (Centron, UK) Vicorder (Skidmore Medical, UK) Cardioscope II (PulseCor, NZ) Arteriograph (TensioMed, HU) 	 Ease of use Patient and doctor familiarity Non operator dependent Possibility for 24 hour ambulatory central BP and in- clinic automated BP (as per Myers) 	 Minimal hard outcome data *Validation (methods and calibration by brachial BP) *strong criticism

Validation studies of brachial cuff central BP devices

paper	DEVICE	Oscillometric recording at	method	calibration	REFERENCE	Nb of sub- jects	Reported error on cSBP in mmHg (m±sd)
Park 2014 [112]	PulseCor R6.5	an and DD1	DM	bration	SphygmoCor calibrated to bSBP and bDBP	1107	3 ± 6
					SphygmoCor calibrated to MAP and bDBP	1107	-5 ± 8
					Invasive pressure tip	6	-5 ± 8
Stoner 2014 [111]	PulseCor R7	30mmHg above SBP	PM	Device own cali- bration	SphygmoCor calibrated to MAP and bDBP	57	-4, 5 ± 2, 4
Agnoletti 2014 [115]	Centron cBP301	(000-000)/2			SphygmoCor calibrated to bSBP and bDBP	33	0.3 ± 3.3
Shih 2014 [102]	Prototype using Microlife WatchBP	60mmHa	TF	LCRD & LDRD	Invasive pressure tip	40	0.1 ± 3.5
	Prototype using Colin VP2000	60mmHa	TE	LCRD & LDRD	Invasive pressure tip	100	-0.6 ± 7.6
Rossen 2014 [108]	Arteriograph	above SBP		bration	Fluid filled catheter	22	4.4 ± 8 .7
Cheng 2013 [106]	Prototype using Microlife WatchBP	60 mmHg	WA	bSBP & bDBP	Fluid filled catheter	85	-4.3 ± 3.5
Shih 2013 [100]	Prototype using Microlife WatchBP	60 mmHg	TF	bSBP &bDBP	Invasive pressure tip	40	-4.2 ± 7.2
	Prototype using Colin VP2000	60 mmHg	TF	bSBP & bDBP	Invasive pressure tip	100	-3.0 ± 7.7
Pucci 2013 [37]	Vicorder	70mmHa	TF	DBP	Fluid filled catheter	50	-4.0 ± 7.4
				bSBP & bDBP			-6.4 ± 7.4
				bSBP & oder	SphygmoCor calibrated to SBP & DBP	90	-6.2 ± 4.6
				bMAP & bD. P	SphygmoCor calibrated to MAP & DBP		-0.5 ± 3.3

Validation studies of brachial cuff central BP devices cont'd

paper	DEVICE	Oscillometric recording at	method	calibration	REFERENCE	Nb of sub- jects	Reported error on cSBP in mmHg (m±sd)
Van Dijk 2013 [116]	Arteriograph	above SBP		bration	Sphygmocor calibrated to bMAP & bDBP		-13.5 ± 15.3
Brett 2012 [67]	Centron cBP301			DBP	Invasive pressure tip	29	0.0 ± 5.9
		(SBP+DBP)/2		bMar DRP	Sphygmocor calibrated to bMAP & bDBP	100	-0.6 ± 3.9
				bSBP & bDBP	SphygmoCor calibrated to bSBP & bDBP		1.6 ± 4.5
Butlin 2012 [103]	SphygmoCor XCEL	10mmHz be 10m DBP	TTE	bration	SphygmoCor calibrated to bSBP & bDBP	30	0.5 ± 1.8
Climie 2012 [71]	PulseCor R6.5	30mmHg above SBP	PM	Device own cali- bration	SphygmoCor calibrated to bMAP & bDBP	47	1.2 ± 2.2
Gunjaca 2012 [70]	Arteriograph	35mmHg above SBP	WA	Device own cali- bration	SphygmoCor calibrated to bSBP & bDBP	1012	8.8 ± 7.3
Lin 2012 [107]	PulseCor R6.5	above SBP		DBP	Fluid filled catheter	37	2.8 ± 3.9
				Device own cali- bration			0.25 ± 6.3
Luzardo 2012 [69]	Mobil-o-graph (ARCsolver)			bration	 SphygmoCor (calibration not specified) 	35	-1.2 ± 3.1
Weiss 2012 [68]	Mobil-o-graph (ARCsolver)	DBP level	TF	Device own cali- bration	SphygmoCor (calibration not specified)	100	0.5 ± 4.5
Numberger 2011 [66]	Arteriograph	35mmHg above SBP	WA	Device own cali- bration	SphygmoCor calibrated to bSBP & bDBP	44	$3.7 \pm np$ (supine) $10.0 \pm np$ (sitting)
Weber 2011 [39]	Mobil-o-graph (ARCsolver)	DBD lovel	TE	DBP	Invasive pressure tip	30	3.0 ± 6.0
				bMAP & bDBP	1		-3.0 ± 9.5
				1 SBP & bDBP			14.4 ± 9.7
				MAP & DL.P	SphygmoCor calibrated to bMAP & bDBP	111	-0.5 ± 4.7
				bSBP & bDb.	SphygmoCor calibrated to bSBP & bDBP		0.3 ± 4.2

Since 2009

- 22 'validation' studies
- 3 different reference standards
 - -14 vs invasive catheter (7 fluid filled)
 - -16 vs non invasive device (all SphygmoCor)
- >10 calibration methods
- Variability range -0.1±3.1 to -13.5±15.3

How do we interpret 'validation' data? How do we know a device will perform clinically better than brachial cuff BP?



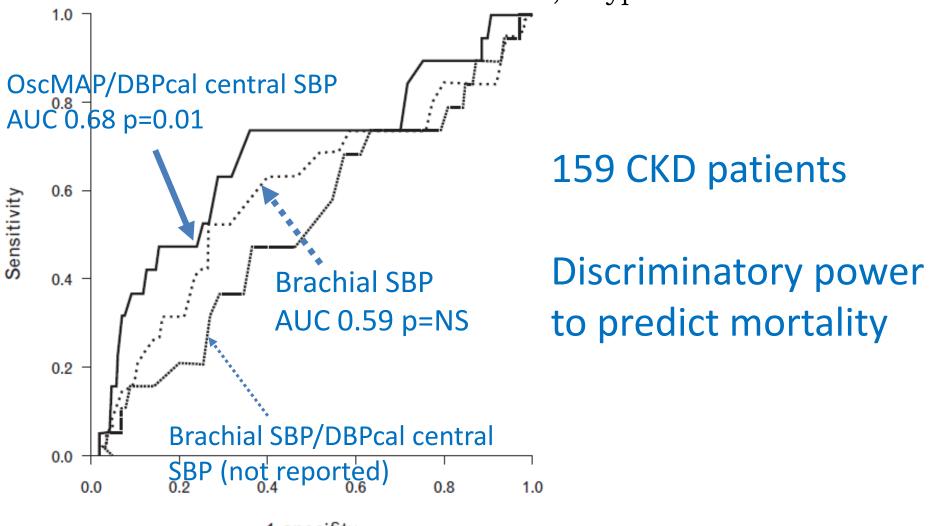
Influence of calibration

Calibration method	Mean difference from invasive cSBP
Brachial oscillometric SBP/DBP	-14.4 ± 9.7
Brachial oscillometric MAP/DBP	3.0 ± 9.5
Invasive MAP/DBP	-3.0 ± 6.0

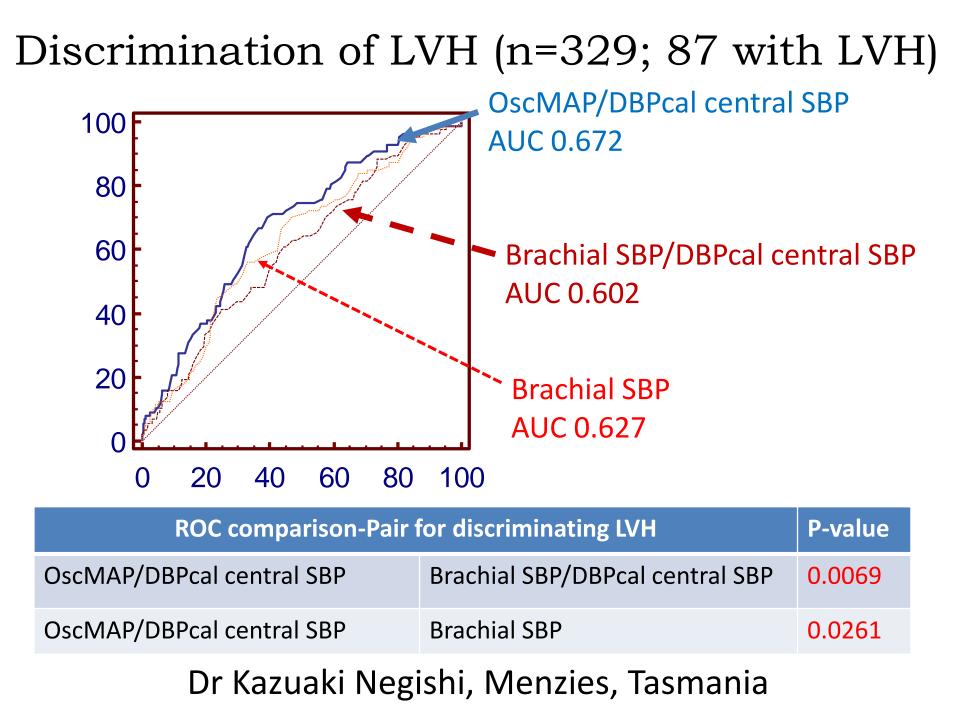
Weber T. et al, Hypertension 2011; 58(5):825-832.

Assessment of systolic aortic pressure and its association to all cause mortality critically depends on waveform calibration

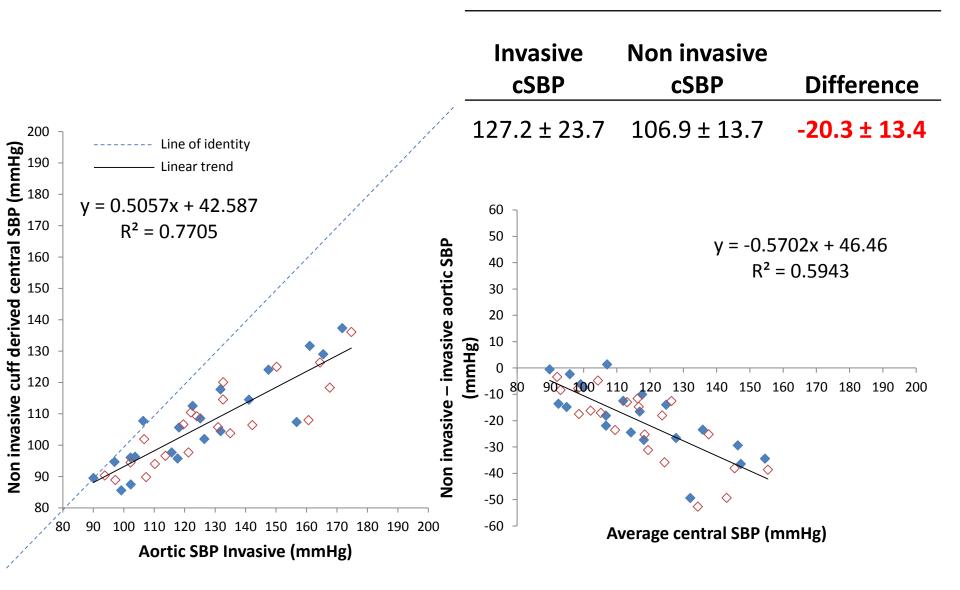
Wasserteurer S. et al, J Hypertension 2015 In Press



1-specifity

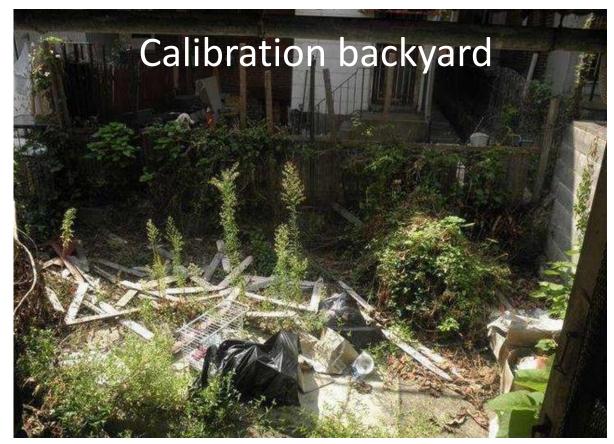


Should all brachial estimated central BP devices be calibrated with oscillometric MAP and DBP to derive a more accurate central SBP estimate? Estimated central SBP (other device calibrated with brachial OscMAP/DBP) vs. invasive aortic SBP



Accuracy of estimated central SBP is influenced by calibration and is device specific

Need international consensus to standardise



Menzies BP Clinic



The Menzies Blood Pressure Clinic is a bulk-billed clinical service operated by the Menzies Institute for Medical Research. This clinic utilises the latest methods dedicated to the investigation and management of high blood pressure.

Patients referred to the clinic undergo various blood pressure testing; including clinic measurements, home measurements and

Menzies Blood Pressure Clinic Referral Form



Private Bag 23, Hobart, Tasmania 7001 Ph: +61 3 6226 4710 Fax: +61 3 6226 7764 email: Menzies.BPClinic@utas.edu.au

For the referral of patients with difficult to treat hypertension for further assessment and management recommendations. All our services are bulk-billed. Please return completed referral form by fax, post or email.

This form is also available electronically as a template for Medical Director and Best Practice software from Tasmania Medicare Local (www.tasmedicarelocal.com.au/search/node/menzies).

Referring Doctor Details

Name		Provider #	
Practice			
Address			
City/Suburb		Post Co	de
Phone	Fax		

Patient Demographic Information

Name		DOB		Gender
Home Address				
City/Suburb			Post Code	
Home Phone		Work Phone		
Mobile	Email			

Health Summary Report

Please provide a brief summary of the patient's health:

Latest clinical BP	Date	Blood pressure
measurements		

Allergies, reactions and other pertinent information

Investigation Results

Please attach any investigations/results pertaining to target organ damage / secondary hypertension (ie renal function tests, echocardiography, ECG, urine ACR, other relevant tests)

Menzies BP Clinic

- Staffed by volunteer specialists
- Bulk billed service (Clinic co-ordinator)
- People with 'difficult to treat hypertension'
- Comprehensive investigation & risk assessment with plan for return to GP care
- Brachial and central 24-hour BP, 7-day home BP, inclinic automated BP (15 min AOBP)
- Underpinned by research (data linkage)



47 y.o male, clinic BP 160/105 mmHg (GP measured) – no current Rx.

15-min AOBP 139/76 mmHg cSBP 129 mmHg

No.	Date	Time	Sys	MAP	Dia	Hr	cSys
1	11/03/15	13:37	140	110	84	65	131
2	11/03/15	13:40	141	110	85	65	133
3	11/03/15	13:42	144	98	60	64	129
4	11/03/15	13:44	138	106	78	65	129
5	11/03/15	13:46	144	106	74	64	133
6	11/03/15	13:48	138	105	77	63	130
7	11/03/15	13:50	137	105	78	64	127
8	11/03/15	13:52	133	101	73	66	124
PLA	AN						

Active management, with personal (lifestyle) in the first instance prior to Rx.

82 y.o male, clinic BP 182/80 mmHg (GP measured) – quintuple therapy; AF

15-min AOBP **155**/83 mmHg cSBP 130 mmHg

No.	Date	Time	Sys	MAP	Dia	Hr	cSys
1	05/03/15	09:30	173	128	90	57	149
2	05/03/15	09:32	168	124	86	56	146
3	05/03/15	09:34	161	121	88	57	
4	05/03/15	09:36	157	117	83	55	132
5	05/03/15	09:38	147	110	79	53	124
6	05/03/15	09:40	145	109	79	54	124
7	05/03/15	09:42	143	108	78	54	118
8	05/03/15	09:44	149	111	78	53	120

PLAN

Well managed. No additional therapy needed.



REVIEW

Central pressure should be used in clinical practice



James E. Sharman*

The identification of some methodological and technical issues could jeopardise progression of the discipline and underscores the imperative for international collaboration to provide guidance.

To be continued.....